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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,448	10/27/2003	Kathleen C.M. Campbell	SIU 7398	8896
321	7590	05/24/2005	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			COOK, REBECCA	
		ART UNIT	PAPER NUMBER	
		1614		

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/694,448	CAMPBELL, KATHLEEN C.M.
Examiner	Art Unit	
Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 28 February 2005.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1,3-33 and 35-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,3-33 and 35-45 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 27 Oct. 2003 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/10/05 2/28/05.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

Claim 1, 3-33, 35-45 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preventing ototoxicity, does not reasonably provide enablement for “treating” or “reducing” ototoxicity for the reasons given in the Paper of October 1, 2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is not seen from the data in the specification that the compound of the claims can be used to treat ototoxicity.

Applicant’s argument regarding “treat” is not persuasive, since “treat” is understood as providing a cure or relief of an existing condition. Furthermore, no data is seen in the specification for to “treating” ototoxicity that has been caused by either a platinum-coordination compound or an aminoglycoside. Amending the claims to recite “preventing or reducing the incidence of ototoxicity” will overcome this rejection.

In view of the amendments to the claims and applicant’s arguments the earlier rejections under 35 USC 112, first paragraph to written description and to scope of enablement regarding all sulfur-containing compounds and under 35 USC 112, second paragraph are withdrawn.

Upon reconsideration, in view of the data on page 19 and in Fig. 1 the earlier rejection under 35 USC 112, first paragraph, to “preventing” is withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-9, 15-26, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,466,678 (Kowabata et al).

Kowabata (column 3, line 1 through column 4, line 8, Test Example 3, claims) discloses a method of using S-adenosyl-L-methionine to reduce nephrotoxicity of a platinum complex compound using the recited orders of administration, routes of administration, dosages and ratios of otoprotective agent to platinum coordination compound. The instant claims appear to differ over Kowabata in reciting a method for preventing ototoxicity. However, it would be inherent that S-adenosyl-L-methionine would prevent ototoxicity caused by a platinum complex compound, since a patient receiving a platinum complex compound is at risk for both nephrotoxicity and ototoxicity and using S-adenosyl-L-methionine to reduce nephrotoxicity would at the same time also prevent ototoxicity caused by the platinum complex compound.

Claims 1, 3-4, 7 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al (Hearing Res., p. 90, 93, 96). Campbell teaches that D-methionine can prevent cisplatin ototoxicity.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-14 and 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al (Hearing Res., p. 90, 93, 96). Campbell teaches that D-methionine can prevent cisplatin ototoxicity.

The instant claims differ over Campbell in reciting orders of administration, routes of administration, dosages and ratios of otoprotective agent to platinum coordination compound. However, once a method of use of a compound is known it is within the skill of the artisan to determine optimum orders of administration, routes of administration, dosages and ratios of compounds to use.

The month of publication of the Campbell reference is not known, but it is noted that it was accepted for publication on 27 August 1996, which is earlier than the date of the priority document 60/027,750, which is October 3, 1996.

#### **Prior Art of Record**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. A number of references submitted by Applicant disclose that L-methionine reduces the toxicity of cisplatin, but do not render the instant invention obvious in the absence of additional information.

#### ***Information Disclosure Statement***

References 19, 23, 33, 53 and 62 were considered to the extent of their English language summary. References 16 and 78-98 were not considered because they are

not publications. The following references were not received and therefore could not be considered: 8, 34-37, 64 and 66.<sup>22</sup>

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,187,817 for the reason given in the Paper of October 1, 2004. Applicant's intent to submit a terminal disclaimer is noted, but it was not received.

Claims 33 and 35-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,265,386 for the reason given in the Paper of October 1, 2004. Applicant's intent to submit a terminal disclaimer is noted, but it was not received.

In view of Applicant's argument the rejection under the judicially created doctrine of obviousness-type double patenting over Application No. 10/694,432 is withdrawn.

### **Conclusion**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Primary Examiner  
Art Unit 1614

May 10, 2005